

**Notice of Allowability****Application No.**

09/514,865

**Examiner**

Sally A Sakelaris

**Applicant(s)**

SHUBER, ANTHONY P.

**Art Unit**

1634

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 1/16/2003.
2. ☒ The allowed claim(s) is/are 1 and 3-5.
3. ☒ The drawings filed on 2/26/00 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.
5. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No. \_\_\_\_\_.
  - (b) ☐ including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the Examiner.
  - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |   |
|---|---|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892)   | 2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)          |
| 3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 4 <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No. _____. |
| 5 <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. <u>1603</u> . | 6 <input checked="" type="checkbox"/> Examiner's Amendment/Comment                  |
| 7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material      | 8 <input type="checkbox"/> Examiner's Statement of Reasons for Allowance            |
|   | 9 <input type="checkbox"/> Other  |

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. Please amend the claims as follows:

a. Amend claim 1 as follows:

1. A method for screening for cancer or adenoma in a patient, the method comprising the steps of:

determining an amount of nucleic acid greater than about 200 bp in length, using an assay that detects said nucleic acid regardless of whether said nucleic acid is mutant or wild-type,  
present in a patient sample comprising shed cells or cellular debris; and

identifying said patient as having cancer or adenoma if said amount is greater than an amount of nucleic acid expected to be present in a sample obtained from a patient who does not have cancer or adenoma.

b. Add new claim 5 as follows:

5. The method of claim 1, wherein said nucleic acid comprises human nucleic acid.

c. It is further noted that the title has been amended to read:

--Methods for the detection of cancer or adenoma--

***Terminal Disclaimer***

The terminal disclaimer filed on July 15, 2003 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patents 6,143,529 and 6,586,177 B1 and also on any patent granted on Application Number 09/545,162 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Sally Sakelaris whose telephone number is (703) 306-0284. The examiner can normally be reached on Monday-Thursday from 6:00AM-5:00PM.

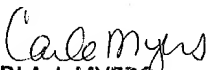
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)308-1119. The fax number for the Technology Center is (703)305-3014 or (703)305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to Chantae Dessau whose telephone number is (703)605-1237.

Sally Sakelaris



7/16/2003

  
CARLA J. MYERS  
PRIMARY EXAMINER